REF 99000943/00 2013-08

Translux® Wave

GB Instructions for use

Table of contents

1	**Application**	**3**
1.1	In general	3
1.2	EC – Declaration of Conformity	3
1.3	Manufacturer’s declaration	3
2	**Instructions on using the unit safely**	**3**
2.1	Explanation of symbols and accompanying word(s)	3
2.2	Transport damage – Unpacking and inspection	4
2.3	Owner’s obligations	4
2.4	Machine journal	4

3	**Intended use**	**4**
3.1	**Description of the device**	5
3.2	Safety requirements	5
3.2.1	General safety instructions on operating the device	5
3.2.2	Safety Precautions	6
3.2.3	BATTERY – Safety precautions	6
3.2.4	BATTERY – Information	7
3.2.5	LIABILITY	8
4	**Unit description**	**8**
4.1	Delivery contents	8
4.2	Description of the control and operating elements	8
4.2.1	Hand piece	8
4.2.2	Alignment key	8
4.2.3	Charging unit	8
4.2.4	Acoustical signals hand piece	9
4.2.5	LED information concerning the radiation emitted	10
5	**Installation and putting into initial operation**	**10**
5.1	Safety requirements during Installation	10
5.2	Connection of the charging unit to the mains power outlet	11
5.3	Inserting the battery into the hand piece	11
5.4	Inserting the fibre optic into the hand piece	12
5.5	Battery charging	12
6	**Operation**	**13**
6.1	Activating and deactivating the exposure cycle	13
6.2	Measurement of the Light Intensity	14
6.3	Sleep Mode	15
6.4	Additional information on the unit operations	15
7	**Alarm conditions**	**15**
7.1	Faulty battery	15
7.2	Faulty LED	15
7.3	Overheat protection	15
7.4	BUILT-IN Temperature overload sensor defective	15
7.5	Battery-low signal	16
8	**Cleaning, disinfection and sterilisation**	**16**
8.1	Disassembly	16
8.2	LIGHT GUIDE – Cleaning and disinfection	16
8.2.1	LIGHT GUIDE – Inspection before the sterilisation	16
8.3	PROTECTIVE LIGHT CONE – Cleaning and disinfection	16
8.3.1	PROTECTIVE LIGHT CONE – Inspection before the sterilisation	17
8.4	LIGHT GUIDE and PROTECTIVE LIGHT CONE – Packaging before the sterilisation	17

8.4.1	LIGHT GUIDE and PROTECTIVE LIGHT CONE – Sterilisation	17
8.4.1.1	Sterilisation method	17
8.4.1.2	Sterilisation parameters	17
8.5	HAND PIECE – Cleaning and disinfection	17
8.6	CHARGING UNIT – Cleaning Casing	18
8.6.1	CHARGING UNIT – Cleaning charging contacts	18
8.6.2	CHARGING UNIT – Replaceable charging contacts	19
9	**Shelf storage**	**19**
10	**Disposal**	**19**
11	**Troubleshooting**	**20**
12	**Technical specifications**	**22**
12.1	Electromagnetic compatibility EN 60601-1-2	23
12.2	Charging unit identification plate	25
12.3	Hand piece serial number	25
13	**Warranty**	**25**
14	**Service**	**26**
14.1	Service agents / Contact in the countries	26
15	**Document history**	**26**

NOTE

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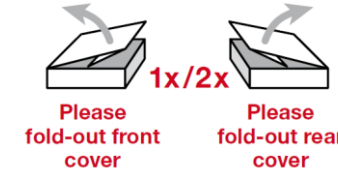

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1 Application

1.1 In general

Translux Wave is a registered trademark of Heraeus Kulzer GmbH.

These operating instructions apply to:

Order no.	Type Features	Date
66055012	Translux Wave – LED Light curing unit	2013-08 / 99000943/00

1.2 EC – Declaration of Conformity

We, Heraeus Kulzer GmbH, Grüner Weg 11, 63450 Hanau, hereby declare that the design, structure and version introduced to the market of the unit described below correspond to the relevant safety and health requirements of the EU Directive.
This declaration shall become invalid in the event of an alteration made to the unit without our prior authorisation.

1.3 Manufacturer's declaration

We hereby confirm that the unit Translux Wave complies with the directive 93/42 EC and the standards IEC 60601-1 and IEC 6060 1-2.

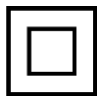
Hanau, 2013-08 – Heraeus Kulzer GmbH, Grüner Weg 11, 63450 Hanau (Germany).

2 Instructions on using the unit safely

Please read this manual and follow its instructions carefully. The words **WARNING, CAUTION and NOTE** carry special meanings and must be carefully reviewed (see the following paragraph). Always keep this manual within easy reach.

2.1 Explanation of symbols and accompanying word(s)

Symbols	Accompanying word(s)	Explanation
	WARNING	Implies that death or serious injury could occur if the advice is not followed.
	CAUTION	Implies that minor injury or device damage could occur if the advice is not followed.
	NOTE	Implies advice that is not related to harm.
	WARNING OF EXPLOSION	WARNING of explosion – observe information and warnings in the chapters and sections marked with the following pictorial symbols.
	DISCONNECT FROM MAINS	WARNING of electric shock. Before carrying out the cleaning and disinfection procedures disconnect the charging base from the electrical power source!
	WEEE	Disposal of old equipment according to WEEE Electrical and Electronic Equipment Act (ElektroG).

		Applied part: Type B applied part-in conformity with technical standards IEC 60601-1.
		Double insulation: Class II device.
		Power supply: Alternate current.
		Direct current.
		Switching power supply plug polarity – Centre positive.
		Use in closed spaces only.
		Device manufactured in conformity with directive 93/42/EEC including technical standards IEC 60601-1 and IEC 60601-1-2.
		WARNING symbol “LED radiation”. Observe the information and dangers in the paragraph 4.2.5.
		Consult instructions for use.
		CAUTION, consult accompanying documents.
		Operating switch: “Start / Stop”.
		Registration certificate according to the ministry of health of the Russian federation.
		Keep away from rain.
		Storage temperature limitation (–20°C (–4°F) to 40°C (104°F)).
		Storage humidity limitation (45% – 85% RH).
		Storage atmospheric pressure limitation (500 – 1060 hPa).

2.2 Transport damage – Unpacking and inspection

The unit is sensitive to shock, because it contains electrical components. Particular care must therefore be taken during transportation as well as storage. The equipment shipped by Heraeus Kulzer was checked thoroughly prior to shipment.
The unit is correctly protected and packed when delivered.
Check the unit for damage after receiving it. If it is damaged, report this to the transportation company within 24 hours of delivery.
Under no circumstances, install or work with a damaged unit and / or accessories.

2.3 Owner's obligations

In addition to complying with the statutory regulations specified, the owner must ensure that statutory requirements are observed a implemented in the workplace, i.e. he must train his personnel and comply with industrial safety legislation and all further valid regulations or laws in force.
For work on and with the unit, written instructions in an understandable form and in the relevant language of the respective employees must be provided by the owner using the operating instructions and on the basis of the work to be carried out.

2.4 Machine journal

We recommend that you keep a "**machine journal**" and document all tests and major work (e.g. servicing, changes) in it.

3 Intended use

The Translux Wave is a LED dental curing light unit intended for use in the oral cavity for the polymerisation of light curing dental materials such as adhesives and filling materials that are activated in the 440 – 480 nm wavelength range.

NOTE

Although most light curing dental materials are activated within this wavelength range, in case of uncertainty, verify the manufacturer's composite specifications or contact the manufacturer.

WARNING – Qualified specialists.

The unit must only be operated by appropriately trained specialist personnel and the dentist (see paragraph 2.3 Owner's obligations). If the unit is used correctly it will not cause any known side effects.

3.1 Description of the device

The Translux Wave uses a source of light consisting of a very-efficient mono-chromatic LED diode with a wavelength comprised between 440 and 480 nm.
The entire light radiated by the Translux Wave is used to activate the camphorquinone photoinitiator.
This produces excellent polymerisation results with a significantly lower heat emission.
The Translux Wave is shipped with a 360° rotating light guide with 8 mm diameter.
The Translux Wave consists of a charging unit and a hand piece, powered by a removable rechargeable Lithium-ion battery.
The hand piece is equipped with a "**Sleep Mode**" to minimise the unit's energy consumption.
The hand piece switches to "**Sleep Mode**" if it is not used for a period of about 5 minutes.

The Translux Wave can operate with two different exposure cycles:

- **Exposure with constant output:** cycle duration 10 seconds.
- **Exposure with slowly increasing output: "Soft-Start"** (cycle duration 20 seconds).
  The "**Soft-Start"** means increase of light intensity from 50% up to 100% within 2 seconds.

NOTE – Observe the exposure times of the materials specified by the manufacturer.

For materials with specific exposure times (e.g. 30 / 40 seconds for dark composites) repeat the exposure several times i necessary.

3.2 Safety requirements

The effectiveness of the safety instructions with regard to personnel protection, handling the unit and handling the processed produ is to a large degree dependent on the behaviour of the staff working with the equipment.

WARNING

Prior to initial operation, carefully read through these Operating Instructions and observe the information in order to avoid errors and subsequent damage, particularly damage to health.
In addition to the instructions in this operating manual, comply with the national laws, regulations, and directives in your country when setting up and operating the unit.

3.2.1 General safety instructions on operating the device

WARNING – INTENDED USE

Use the unit only for the purpose for which it is intended (see paragraph 3 Intended use). Any other uses are strongly contra-indicated. Any non-compliance of this regulation can result in serious injury of the patients or operators of the unit a well as damage or faults to the unit. Heraeus Kulzer is not liable for consequential damages due to the non-observance o the aforementioned provision!

WARNING

The user is responsible for testing the Translux Wave for its use and suitability for the intended purposes.

***Never** point the light towards the eyes! Direct or indirect exposure of light into the eyes must always be prevented by wearing protective goggles that filter out blue light. When curing, position the light guide tip directly over the material that needs to be cured and avoid extraneous exposure to soft tissues. Eyes, gums, soft tissue and other body parts must not b exposed to the blue light (if necessary, these parts must be covered with protection). Use a rubber dam to protect the soft tissues, i.e. gingiva during treatment. Exposure must be restricted to the area of the oral cavity in which clinical treatment executed.*

WARNING – CONTRA-INDICATIONS

***Do not** use the Translux Wave on patients fitted with a pacemaker or other implantable electronic devices. This also appli to the operator.*

The unit must not be used by children, the blind or the deaf and also not by / on persons who are prone to possible epilept seizures. The above pre-named persons may not recognise the risks of use and operation. Due to safety reasons for the operator and the patients with potential risk of epileptic seizures, use and operation of the device is prohibited.

WARNING

No modification of this equipment is allowed.

The owner / user must ensure that:

– The unit is not used on patients with a positive anamnesis after light testing, for example with urticaria solaris and / o porphyria as well as on patients who have been treated with photosensitising medication.

- The unit is not used on patients that have had surgery for eye cataracts, which are particularly sensitive to light, unle they use suitable protective measures, such us the use of eye protectors / spectacles that filter out blue light.
- Patients whose anamnesis includes retinal diseases must have treatment with Translux Wave authorised by their ophthalmologist.
- A specialist doctor is consulted in all potential risk cases.

WARNING – Control of infections.

The light guide and the protective light cone must be cleaned, disinfected and sterilised (steam) before every use.
The light guide and the protective light cone are delivered in ***NON STERILE*** *condition and must be sterilised before being used for the first time. See paragraph 8.4.1.2 Sterilisation parameters.*

3.2.2 Safety Precautions

WARNING – RISK OF EXPLOSION

Do not *install the device where there is the risk of explosions.*
The device must not be used where an inflammable atmosphere is present (anaesthetic mixtures, oxygen, nitrous oxide, etc.). Use the device in a well ventilated area.

WARNING

Before using the unit, check the mains power cable and plug for damage. If they are damaged, do not connect the unit to the mains.

Use only original spare parts or accessories from Heraeus Kulzer GmbH. Heraeus Kulzer provides a light guide suitable f use with the Translux Wave. Other light guides must not be used. Heraeus Kulzer GmbH will not accept any liability for damage resulting from the use of non original Heraeus Kulzer spare parts or accessories.

3.2.3 BATTERY – Safety precautions

Heraeus Kulzer GmbH assumes no liability for battery problems that occur when the Safety Precautions listed in the paragraph below are not carefully adhered.

WARNING

Misusing the battery may cause the battery to get hot, rupture, or ignite and cause serious injury. Be sure to follow the safety rules listed in the below paragraph.

Use original Heraeus Kulzer batteries only!

The use of non Heraeus Kulzer batteries or non-rechargeable batteries and / or primary batteries is a potential danger an can damage the device.

Keep the battery out of the reach of children!

Never *open, puncture or crush the battery – it contains poisonous substances.*

If the battery shows corrosion, emits an unusual smell, or loss of fluids, remove the battery from the hand piece immediat

Do not *expose the battery to water or salt water, or allow the battery to get wet. Do not store the battery in high humidity o in a place which may expose the battery to rain.*

In the event that the battery leaks and the fluid gets into one's eye, do not rub the eye. Rinse well with water and immediately seek medical care. If left untreated the battery fluid could cause damage to eye.

WARNING – RISK OF EXPLOSION

Use only the Translux Wave charging unit and the input power supply, which are provided with the unit, to charge the han piece's battery. Never attempt to charge the Translux Wave battery by using any other charging unit. The use of any othe charging unit can result in the damage of the battery, risk of explosion and fire!

***Never** use the Translux Wave recharging unit to charge other types of battery or other units with a rechargeable battery! Use only original batteries from Heraeus Kulzer.*

***Do not** pierce the battery with any sharp objects, strike the battery with a hammer / tools, step on the battery, or otherwise subject it to strong impacts or shocks.*

***Do not** place the battery in fire or apply heat to the battery. Never short circuit the end elements of the battery with any me objects due to the risk of burns, fire and explosion. Never carry or store the battery together with necklaces, hairpins, or other metal objects.*

WARNING – Do not disassemble or modify the battery!

Safety mechanisms are incorporated in the battery which if damaged may cause the battery to generate heat, rupture, explode or ignite.

WARNING – Do not place the battery on or near fires, or other high-temperature locations.

***Do not** place the battery in direct sunshine. Doing so may cause the battery to generate heat, rupture or ignite. Using the battery in this manner may also result in a loss of performance and shortened life expectance.*

WARNING – In case of fire, DO NOT THROW WATER ON A BURNING BATTERY!

A class C fire extinguisher (according to European Regulation EN 3) must be used.

WARNING – Damaged or exhausted battery disposal.

Dispose a damaged or exhausted battery after taking the necessary steps to prevent external short circuit by the following method:

After having insulated the terminals of the battery with insulating tape, dispose off under the law or in accordance with the local council.

3.2.4 BATTERY – Information

- **Time to charge empty or new battery: approx. 3 hours.**

NOTE – NEW Battery: first charging

*For the first charge, this process will take about **3 hours**. New batteries or batteries stored for a long time may take more time to charge. The battery will reach its full capacity after a few full charge / discharge cycles.*

NOTE

Place the hand piece into the charging unit after each treatment, or when not in use.

- **Operating condition:**
  Operating temperature: 10°C (50°F) up to 35°C (95°F).
  Relative humidity: 45% to 85% RH.
  Atmospheric pressure: 800 hPa to 1060 hPa.

CAUTION

The temperature and relative humidity ranges over which the battery can be charged is 10°C (50°F) to 35°C (95°F), and 45% to 85% RH. Charging the battery at temperatures outside of this range may cause the battery to become hot or damaged. Charging the battery outside this temperature range may also harm the performance of the battery or reduce th battery's life expectancy.

- **Battery transportation and storage conditions:**
  Recommended temperature and relative humidity ranges:
  –20°C (–4°F) to 40°C (104°F) and 45% to 85% RH.
  Always store the battery charged and not for longer than 5 months.
  Ambient air pressure: 500 hPa to 1060 hPa.

NOTE

Always fully charge the battery before an extended period of inactivity of the device and at least once every 5 month In case of extended period of inactivity replace the battery from the hand piece.

- **Battery Typical Life Characteristics:**
  The Translux Wave battery has a typical life expectancy of 300 – 400 charging cycles depending on the application and environmental conditions in which it is used.

NOTE

The battery is a chemical product utilising a chemical reaction, so the performance will deteriorate not only through u but also with the passage of time even if it left unused.

3.2.5 LIABILITY

Work on electronic equipment in the unit must be carried out by **Heraeus Kulzer, Heraeus Kulzer service partners or qualified, specialist personnel only** and when the equipment is in a safe status (de-energised).

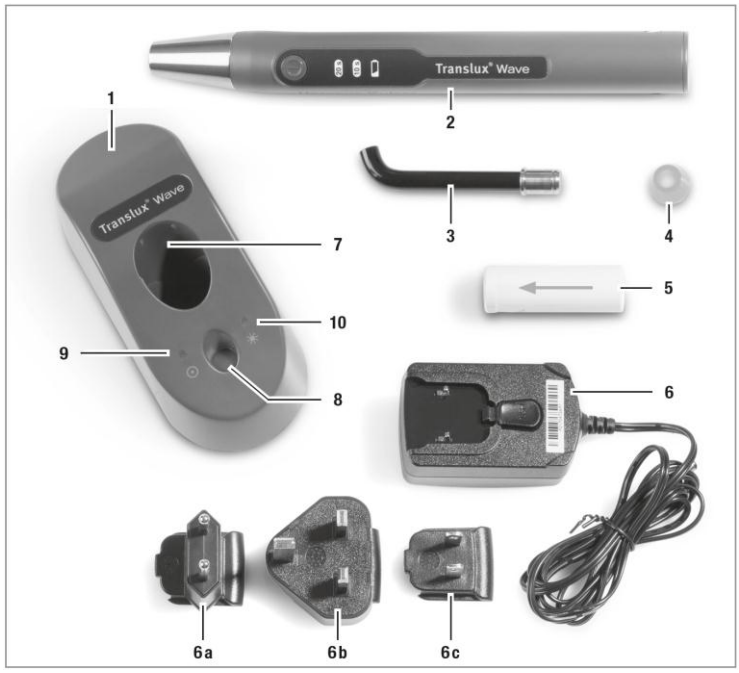
Only use authorised original spare parts and accessories.
Avoid other parts as they hide unknown risks.

The operability and safety of the unit is only guaranteed if the necessary tests, maintenance and repair work is carried out by **Heraeus Kulzer, Heraeus Kulzer service partners or trained, specialist personnel.**

For possible damage coming from a fault / malfunction of the unit due to improper repair, which was not carried out by **Heraeus Kulzer service partners or by personnel trained by us** or in cases where original spare / accessory parts were not used during a pa replacement, Heraeus Kulzer GmbH is **not liable.**

4 Unit description

4.1 Delivery contents



1 Charging unit

2 Hand piece

3 Light guide, Ø = 8 mm

4 Protective light cone

5 Rechargeable Lithium-ion battery pack

6 Universal input power supply (100 V – 240 V (~)) including international mains socket adapters:

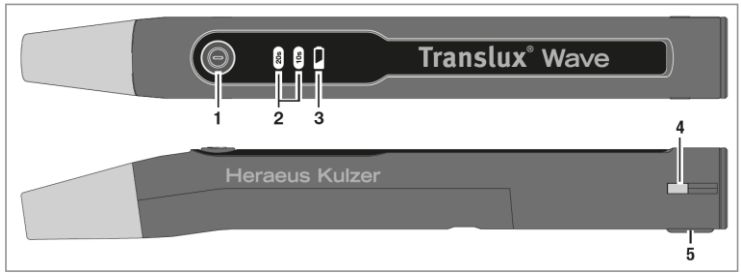
6a = Europe type 1

6b = UK type 2

6c = US / JP type 3

4.2 Description of the control and operating elements

4.2.1 Hand piece



1 "**Start / Stop**" button

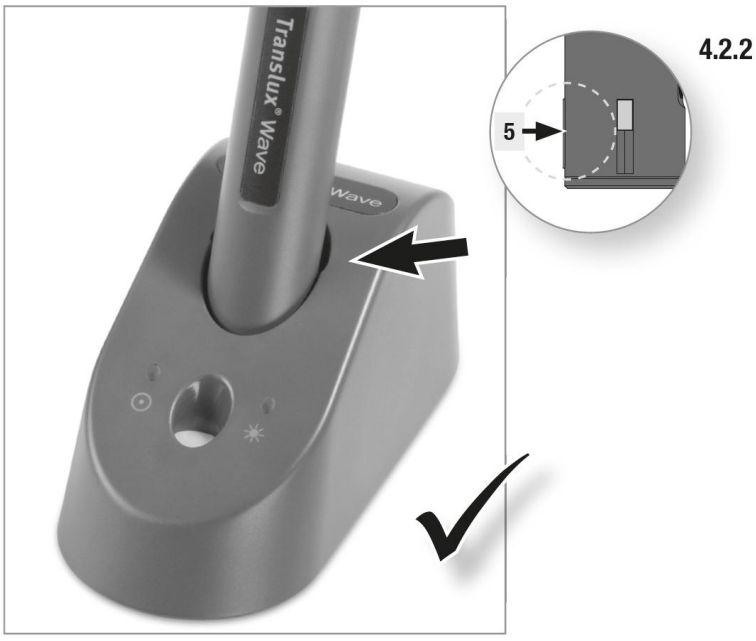
2 Curing modes LEDs (GREEN)

3 Battery status LED (**2-colour:** GREEN / YELLOW)

4 Charging unit contacts

5 Alignment key

4.2.2 Alignment key

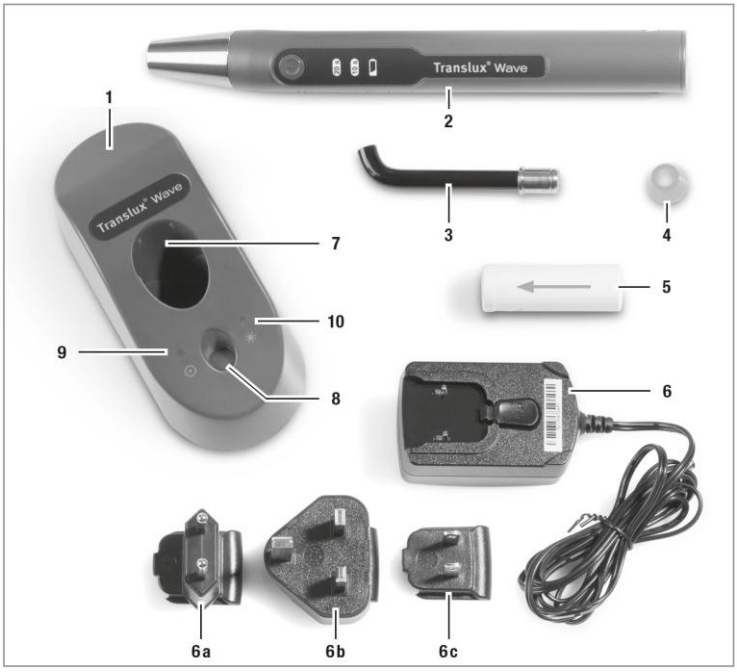


The alignment key (**5**), located at the back bottom part of the hand piece's case, allows the correct insertion of the hand piece in th charging unit holder.

When inserting the hand piece into the charging unit, the alignment key must be aligned with the guiding slot positioned inside the charging unit. **A beep confirms that the contacts are in the correct charging position!**

4.2.3 Charging unit

Top view elements



1 Charging unit cover

7 Hand piece holder with alignment key and replaceable charging unit contacts

8 Light intensity sensor

9 ⊙ – GREEN colour LED

Function: It indicates the charging unit is powered up.

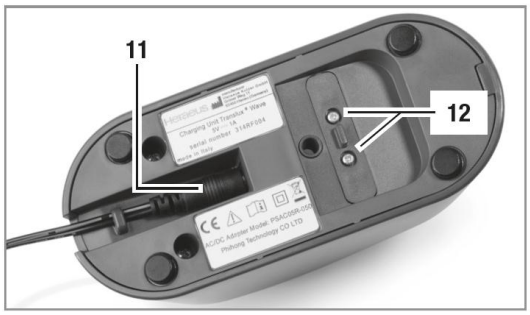
10 ☀ – 2-colour LED (GREEN / YELLOW)

Function: Light intensity information.

GREEN: Indicates that the light intensity, measured with the built-in light meter is suitable for effective treatment.

YELLOW: Indicates that the light intensity is insufficient.

Bottom view charging unit



11 Power supply socket

12 Replaceable charging contact insert

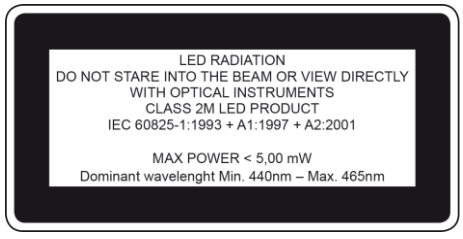
4.2.4 Acoustical signals hand piece

Function / Error Condition	Hand piece Button operation	Acoustic signal/s emitted Indications on the hand piece
POLIMERISATION PROGRAM: 10 seconds.	• Press the "**START / STOP**" button briefly to start the exposure.	• **1 beep** when pressing the "**START / STOP**" button. • **1 beep** at the end of exposure time. **The green LED 10 second light on.**
"SOFT-START" PROGRAM: 20 seconds.	• Press the "**START / STOP**" button for at least one second to start the exposure.	• **1 beep** when pressing the "**START / STOP**" button. • **1 beep** after 1 second for acoustic indication of **"Soft-Start"**-mode activation. • **1 beep** after 10 seconds of exposure time. • **1 beep** at the end of exposure time. **The green LED 20 second light on.**
INTERRUPTION OF THE EXPOSURE CYCLE	• The exposure cycle can be interrupted at any time and program in use by pressing the "**START / STOP**" button .	• **1 beep** when pressing the "**START / STOP**" button.
BATTERY-LOW SIGNAL The residual charge level of the battery is sufficient for a few exposure cycles.		• **2 beeps** at the end of the exposure cycle. • Battery icon is blinking green. **Place hand piece into charger base**

		for charging!
SIGNAL WHEN BATTERY EMPTY Following exposure cycle can't be activated.		• **2 beeps** without activation of exposure cycle. • Battery icon is blinking green. **Place hand piece into charger base for charging!**
DEFECTIVE BATTERY SIGNAL		Only with hand piece placed into the charging unit. • **1 beep** every second for a period of 30 seconds. **The battery status LED lights YELLOW.**
LED Light source defective		No acoustical signal emitted. **The green exposure cycle LED in use blinks.**
OVERHEATING CONDITION		• **3 beeps**, and the electronics allows termination of the exposure cycle in use.
BUILD-IN Temperature overload sensor defective		• **4 beeps** at the start of an exposure cycle.
Charging circuit of the hand piece defective **Note:** This condition is detected only with hand piece placed inside the charging unit.		**Two green LED (10 s / 20 s) on the hand piece blinking.**

4.2.5 LED information concerning the radiation emitted

This device uses high-luminosity LEDs, Class 2M (IEC 60825-1).


LED RADIATION
DO NOT STARE INTO THE BEAM OR VIEW DIRECTLY
WITH OPTICAL INSTRUMENTS
CLASS 2M LED PRODUCT
IEC 60825-1:1993 + A1:1997 + A2:2001
MAX POWER < 5,00 mW
Dominant wavelenght Min. 440nm – Max. 465nm

LED Radiation.

Do not stare into the beam or view directly with optical instruments.

- Class 2M LED Product.
- IEC 60825-1:1993 + A1:1997 + A2:2001.
- **Max. power:** < 5.00 mW.
- **Dominant wavelength:** Min. 440 nm – Max. 465 nm.

WARNING

Diverging beams

Do not *observe the emission of light from the LED using optical instruments such as monocles, magnifying glasses or microscopes from a distance of less than 100 mm as this could cause a risk of damage to your eyes.*

Collimated beams

Do not *observe the emission of light from the LED using optical instruments designed for use at a distance, such as telescopes or binoculars, since this could cause a risk of damage to your eyes.*

In the event of the LED control circuit failure, the LED radiation emission cannot exceed the value in the normal use condition of the medical equipment.

Labels are provided on the packaging of the device, as indicated in the figure here above.

5 Installation and putting into initial operation

The following sections of this paragraph contain the information and instructions which must be followed to ensure successful and faultless operation of the device.

Before operating the Translux Wave follow the instructions in the sequence described below.

The medical system is in compliance with the safety standards only if it is installed by following the instructions described here belo

The device must be installed in a suitable place that is handy for its use. Place the charging unit on a sturdy, dry, flat and horizonta surface.

IMPORTANT

The hand piece is intended for use within the patient environment whereas the charger unit and the Switching Power Sup adapter are not intended for use within the patient environment.

NOTE

The patient environment is defined as an area 1.5 m from the patient (as per IEC 60601-1, third edition and IEC 60601-1-

WARNING

Always inspect the unit and its components for any damage before installation.

If damage is apparent, do not proceed with the installation of the device.

The operator must not come simultaneously into contact with the elements outside the patient environment (charger units and switching power supply adapter) and the patient.

Do not connect other external components to the medical system.

5.1 Safety requirements during Installation

WARNING

The electrical installation of the premises where the device is installed and used must comply with existing legislation and the safety specifications relevant to power systems.

Install the device in a place where it will be protected from blows and from accidental splashes of water or other liquids. D not expose the device to direct sunlight, UV light.

Do not *install the device on top or close to sources of heat. When installing, make sure that there is adequate air circulati around the device. Do not install the device close to solvents or flammable liquids as they could damage the plastic casin of the device.*

The plug of the Switching Power Supply (Direct Plug-In), model PSAC05R-050, is considered the mean of isolating of the medical equipment from supply mains. When the plug is connected, the power supply adapter must be easily accessible.

Leave sufficient free space around it. The medical equipment shall not be positioned to make difficult to operate on the disconnection device (so on the plug of the Switching Power Supply).

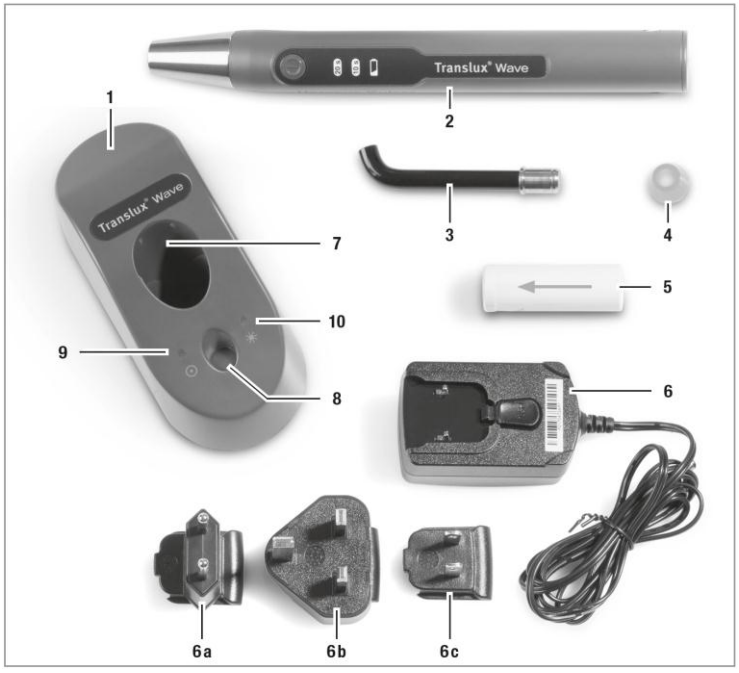
***Never** short circuit the end elements of the battery with any metal object as it could cause a risk of burns, fire and explosi*

*The device is transportable but it must be handled with care. Transport the device in a horizontal position. **Do not** let the device be exposed to shaking or vibrations. For sizes and weight see paragraph 12 (Technical specifications).*

WARNING – RISK OF EXPLOSION

***Do not** install the device where there is the risk of explosions. The device must not be used where an inflammable atmosphere is present (anaesthetic mixtures, oxygen, nitrous oxide, etc.). Install the device in a well ventilated area.*

5.2 Connection of the charging unit to the mains power outlet



The Translux Wave is supplied with a separated universal-input unit (**6**) that accepts 100 to 240 V (~), 50 / 60 Hz.

WARNING

*Before connecting the charging unit (**6**) to the mains network, check carefully that the voltage and frequency of the mains network correspond to the values stated on the rating plate of the device. The rating plate is fitted to the bottom of the charging unit.*

Use only the switching power supply adapter which is provided with the device. The use of any other power supply adapte can result in damage of the battery.

Do not connect the switching power supply adapter to the mains socket by using a multiple portable socket-outlet.

NOTE

The Translux Wave power supply unit (6) is supplied with three interchangeable adapters:

Fig. (6 a) = Europe type 1

Fig. (6 b) = UK type 2

Fig. (6 c) = US / JP type 3

1 Select the correct adapter between the ones available: Europe – Type 1, UK – Type 2, US / JP – Type 3.

2 Each adapter has a slot into which the retaining latch on the power supply unit fits.

3 With the slot oriented toward the power supply unit, place the adapter onto the power supply unit so that the slides on the adap are aligned with their respective slots on the power supply unit.

4 Pressing down on the adapter and power supply unit, slide the adapter into the power supply unit until a click is heard and the adapter is locked in place.

NOTE

Pressing down on the adapter during installation ensures that all the slides are held by the retainers on the power sup unit. If the adapter feels loose, remove it and re-install.

5 To remove the adapter from the power supply unit, press the latch retainer button (marked with the word "**PUSH**") and slide the adapter away from the power supply unit and remove the adapter.

6 Retain unused adapters for future use.

7 Connect the plug of the power cord into the socket on the underside of the charging unit.

WARNING

Check the power cable, the power supply unit and the adapter regularly to make sure that they are in good condition.
If damage is apparent do not use damaged part until it is replaced.
Use original Heraeus Kulzer spare parts and accessories only.

8 Plug the power supply unit with its adapter into the mains power outlet.

9 The GREEN LED on the charger unit will light up (icon ⊙).

5.3 Inserting the battery into the hand piece

The Translux Wave is supplied with a powerful Lithium-ion rechargeable battery.

The battery is supplied separately in the device packaging and must be inserted into the hand piece before initial operation.

WARNING

Carefully follow all the safety precautions described in the paragraph 3.2.3 (BATTERY – Safety precautions).

CAUTION

***NEVER** place the hand piece in the charging unit without the battery inserted in the hand piece.*

Insert the battery into the hand piece in the sequence described below:

1 Remove the battery from its packaging.

WARNING

Never *short circuit the terminals of the battery with any metal object as it could cause a risk of burns, fire and explosio*

2 Use a flat tool (for example a coin) to unscrew counter-clockwise the battery cap of the hand piece **(Fig. 1** and **2).**

3 An arrow is marked on the battery case **(Fig. 3).**

NOTE

This arrow indicates the orientation with which the battery must be inserted into the hand piece.

4 Slowly slide the battery with the arrow oriented toward the housing into the hand piece until it stops **(Fig. 4).**

NOTE

If the battery is inserted in the wrong way (i.e. in the opposite direction of the arrow), the hand piece will not function. In case the battery is inserted in the wrong way, no damage is caused to the hand piece's electronics.

WARNING

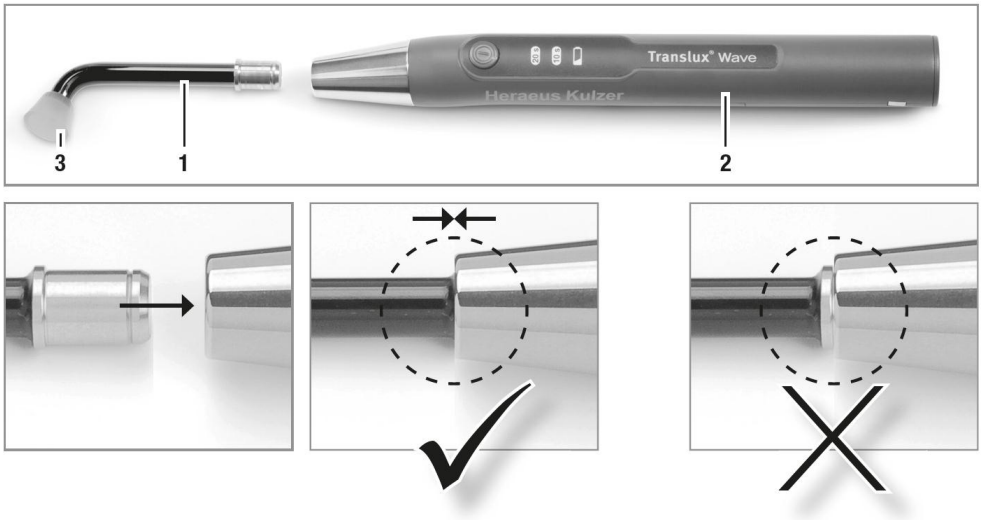
Use original Heraeus Kulzer batteries only. The use of other manufacturer batteries or non-rechargeable batteries / primary batteries is a potential hazard and can cause irreversible damage to the unit.

5 Use a flat tool (for example a coin) to screw clockwise the battery cap of the hand piece.

NOTE

The unit will not function properly if the cap of the hand piece is not screwed on completely.

5.4 Inserting the fibre optic into the hand piece



- Rotate the light guide slightly (**1**) and insert it into the hand piece (**2**) until final positioning is reached.
  The final position is reached when you hear a "**click**".
- Mount the protective light cone (**3**) on the top end of the light guide.

Positioning the light guide

- Rotate the light guide into the desired position for the polymerisation.
- To make full use of the light intensity provided, place the light guide as close to the composite as possible.

Avoid direct contact with the composite material!

CAUTION – Keep the light guide clean at all times to obtain full light intensity.

The light intensity is considerably reduced if:

- The light guide is not in perfect condition (scratched or chipped).
- The light guide is not correctly placed in the hand piece.
- The light guide has composite stains.

WARNING

A damaged light guide reduces the light intensity and must be replaced with a new one immediately. Sharp edges may cause serious injury. Use original Heraeus Kulzer light guides only.

WARNING – Infection control:

To make treatment as safe as possible for patients and operators, the light guide and the protective light cone must be cleaned, disinfected and sterilised before each treatment. Follow the instructions listed in paragraph 8 (Cleaning, disinfection and sterilisation) step by step.

5.5 Battery charging

CAUTION – NEW Battery: first charging

The Translux Wave battery has been partially charged at the factory.
Therefore the battery must be fully charged before using the Translux Wave for the first time.

NOTE – NEW Battery: first charging

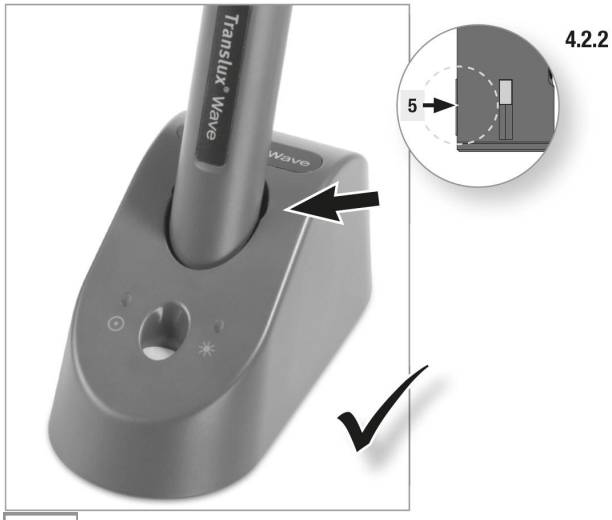
*For the first charge, this process will take about **3 hours.** New batteries or batteries stored for a long time may take longer*
charge. The battery will reach its full capacity after a few full charge / discharge cycles.

WARNING – RISK OF EXPLOSION

Use only the charging unit, supplied with the Translux Wave, to charge the battery. Never attempt to charge the battery using another battery charging unit or power source, due to risk of explosion and fire.

Insert the hand piece with the battery into the Translux Wave charging unit.

A beep confirms that the contacts are in the correct charging position!



IMPORTANT NOTE – Alignment key

The alignment key (**5**), located at the back bottom part of the hand piece's case, allows the correct insertion of the hand piece in the charging unit. When inserting the hand piece into the charging unit, the alignment key must be aligned with th slot positioned inside the charging unit.

Battery charging process.

- The Green battery status LED, on the hand piece, starts blinking.
- When the charging phase is complete, battery fully charged, the Green status LED is permanently lighted up.

IMPORTANT NOTE – Defective battery

In case, during the charging phase, the hand piece electronics detects a battery malfunction, the changing process is interrupted and the status battery LED will blink YELLOW in colour.

In this condition, a **beep** signal is emitted every second for a period of 30 seconds.

Replace the defective battery with a new one!

WARNING

Use Heraeus Kulzer batteries only!

NOTE

*When the hand piece is placed in the charging unit its functioning is inactive. The operativeness of the "**Start / Stop**" butto*

is prevented.

The hand piece can be removed from the charging unit during the charging process; however, the battery may not be fully charged and may shorten the operational duration.

6 Operation

WARNING – Check the condition of the device before starting the treatment.

Before each treatment, always make sure that the device is in proper working order and that the accessories (light guide and protective light cone) are efficient. If anything is noted during treatment, do not carry out the treatment and contact Heraeus Kulzer or a local authorised Customer Service agent (see paragraph 14 Service). Do not use the device and its accessories if damage is apparent. Prior to each use of the Translux Wave ensure that the emitted light intensity is sufficie to guarantee the polymerisation. Check the light intensity by using the light meter integrated into the charging unit (see paragraph 6.2 Measurement of the Light Intensity).

WARNING – Control of infections

First use

*The accessories, light guide and protective light guide, are delivered in **NON STERILE** condition and must be sterilised before being used for the first time.*

Every use

Once used, the accessories, light guide and protective light guide, must be reprocessed prior to reuse, according to the procedures described in the paragraph 8 (Cleaning, disinfection and sterilisation).

6.1 Activating and deactivating the exposure cycle

The Translux Wave can operate with two different exposure cycles:

– **Exposure with constant output:** cycle duration 10 seconds.
– **Exposure with slowly increasing output: "Soft-Start"** (cycle duration 20 seconds).
The "**Soft-Start"** means increase of light intensity from 50% up to 100% within 2 seconds.

- If the hand piece is in "**Sleep Mode**" (all the curing mode LEDs on the hand piece are OFF), briefly press the "**Start / Stop**" butto to make the hand piece operative. (After restarting, the 10 second LED will light up by default).

Exposure 10 seconds polymerisation

Briefly press the "**Start / Stop**" button . The light emission will turn on.
The 10 second LED is on showing that this program is running.
Once the curing cycle is complete, the unit will automatically turn the light off.

Acoustical signal:

The following acoustical signals (beep) are emitted:

1 beep while press the "**Start / Stop**" button.

1 beep at the end of the exposure time.

Exposure 20 seconds "Soft-Start" polymerisation

Press and keep pressed for at least one second the "**Start / Stop**" button . The light emission will turn on.
The 20 second LED is on showing that this program is running.
Once the curing cycle is complete, the unit will automatically turn the light off and the unit returns to the 10 second mode (10 second LED on).

Acoustical signal:

The following acoustical signals (beep) are emitted:

1 beep while press the "**Start / Stop**" button.

1 beep after 1 second for acoustic indication of **"Soft-Start"**-mode activation.

1 beep after 10 seconds of exposure time.

1 beep at the end of the exposure time.

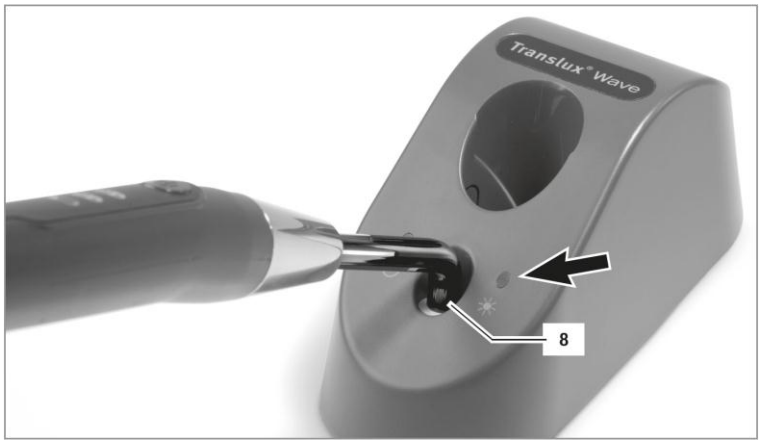
NOTE

The exposure cycle can be interrupted at any time, before the exposure time is over, by pressing again the "**Start / Stop**" button.

Acoustical signal:

An acoustical signal (**beep**) is emitted, when the "**Start / Stop**" button is pressed to interrupt the cycle.

6.2 Measurement of the Light Intensity



The charging unit of the Translux Wave is equipped with an integrated light intensity meter (**8**).

CAUTION

Before each treatment always check the light intensity by using the light intensity meter integrated in the Translux Wave charging unit.

- Without applying pressure, place the light guide flat and directly on the testing area (**8**).

Activate the unit by pressing the "**Start / Stop**" button (whichever exposure time selected).

The light intensity measuring is immediately indicated by the 2-colour LED (Symbol ☀) placed at the bottom right of the testin area.

GREEN LED: The light intensity is sufficient for the treatment.

YELLOW LED: The light intensity is insufficient and patient/s must not be treated.

CAUTION

If the light intensity is insufficient to carry out the following controls and measures:

- The light guide has not been inserted into the hand piece (see paragraph 5.4 Inserting the fibre optic into the hand piece).
- Check the light guide for contamination or defects.
- Clean the light guide of any contamination (see paragraph 8 Cleaning, disinfection and sterilisation) or replace the damaged light guide with a new one.

Use original Heraeus Kulzer light guides only.

WARNING

If the measures described above do not result in any improvement, do not use the device for any treatment. Switch of the unit (disconnect the charging unit from the electrical power source) and ensure that unauthorised unit re-activation not possible. Contact a Heraeus Kulzer's service partner, or technically trained personnel authorised by Heraeus Kulz (see paragraph 14 Service).

6.3 Sleep Mode

The hand piece is equipped with a "**Sleep Mode**" to minimise the unit's energy consumption.

Outside the charging unit, all internal functions of the hand piece are automatically turned off ("**Sleep Mode**") if it is not used for approximately 5 minutes.

In "Sleep Mode" the curing modes LEDs on the hand piece are turned off.

To terminate the "**Sleep Mode**" press the "**Start / Stop**" button . The hand piece is ready for operation.

6.4 Additional information on the unit operations

NOTE

If the hand piece is placed in the charging unit before the curing cycle is terminated, the light emission automatically switches off.

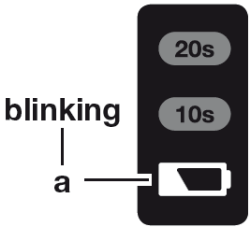
*When the hand piece is placed in the charging unit its functioning is inactive. The operativeness of the "**Start / Stop**" butto*

is prevented.

The Translux Wave is equipped with microprocessors which continuously check the optimum charging parameters of the battery. After every treatment, the hand piece should therefore be inserted in the charging unit for storage irrespective of battery level.

7 Alarm conditions

7.1 Faulty battery



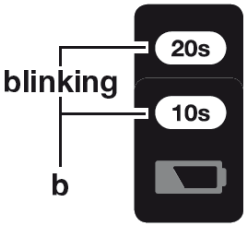
In the case of a defective battery, the Battery status LED on the hand piece will continuously blink YELLOW (**Fig. a**).

A "**beep**" sound is emitted every second for a period of 30 seconds.

IMPORTANT

This error condition is detected only when the hand piece is placed in the charging unit.

7.2 Faulty LED



When a malfunction LED condition is detected by the microprocessor, the green curing mode LED which is in use starts blinking (**Fig. b**).

7.3 Overheat protection

If multiple curing cycles in rapid succession occur (normally after 18 consecutive cycles, each lasting 20 seconds), the built-in temperature overload sensor may activate.

Once the overheat protection activates, an acoustical signal (**3 beeps**) is emitted at the end of the exposure cycle.

The activation of the overheat protection temporarily stops the use of the unit for a few minutes.
Allow the hand piece to cool down for at least 4 – 5 minutes, then start the next exposure by pressing the "**Start / Stop**" button .

NOTE

*The hand piece upon reaching operational temperature. **No "manual reset"** required.*

7.4 BUILT-IN Temperature overload sensor defective

In case of a defective temperature overload sensor, "**4 beeps"** are emitted at the start of an exposure cycle.

NOTE

If the temperature overload sensor fault occurs during an exposure cycle, the software allows completing the exposure.

*No further exposure cycle is allowed by pressing the "**Start / Stop**" button* *and "**4 beeps**" are emitted.*

Any further operation with defect temperature overload sensor is prevented.

7.5 Battery-low signal

When after frequent use the battery charge drops to the minimum level, the Translux Wave microprocessor permits another few cycles in any curing mode, without re-charging the battery.

This condition is signalled at the end of each cycle by "**2 beeps**".
Battery icon is blinking green. **Charge the battery!**

At the end of a few cycles the remaining battery charge does not allow any further exposure cycle. This condition is signalled by "**2 beeps**".
Battery icon is blinking green. **Charge the battery!**

8 Cleaning, disinfection and sterilisation

DISCONNECT FROM MAINS

Before carrying out the cleaning and disinfection procedures disconnect the charging base from the electrical power sour

WARNING

Control of infections

*The light guide and the protective light cone are delivered in **NON STERILE** condition and must be cleaned, disinfected a sterilised (steam) before being used for the first time as well as before every use.*

***Do not** sterilise the hand piece and the charging unit!*

***Do not** sterilise the battery!*

8.1 Disassembly

- Remove the protective light cone from the light guide.
- Remove the light guide: Rotate the light guide slightly and pull it out from the hand piece.

8.2 LIGHT GUIDE – Cleaning and disinfection

CAUTION

Do not *use sharp or pointed instruments to clean the light guide, since they could scratch the surface of the light guide an thus decrease light transmission.*

Do not *use cleaning / disinfectant agents containing organic, mineral and oxidising acids, hydrogen peroxide, chloride, iodine, bromide and solvents.*

1) Immediately after use, any possible residue, such as composite material, must be removed from the end surface of the light guide. Any polymerised composite should be removed by using ethanol and a plastic spatula or soft nylon brush may help in removing the material residue.
2) Disinfect the light guide with a clean, soft lint free cloth dampened with a mild disinfectant solution, featuring a mild pH (pH 7), according to the manufacturer's specifications. **Allow the disinfectant solution to dry.**

8.2.1 LIGHT GUIDE – Inspection before the sterilisation

Before proceeding with the sterilisation process, carefully check the light guide for damaged surfaces, discolouration and contamination.

WARNING

Do not *use a damaged light guide. If damage is apparent, replace the light guide with a new one.*

If the light guide is still contaminated, repeat the cleaning and disinfection procedure.

8.3 PROTECTIVE LIGHT CONE – Cleaning and disinfection

CAUTION

Do not *use cleaning / disinfectant agents containing organic, mineral and oxidising acids, hydrogen peroxide, chloride, iodine, bromide and solvents.*

- Clean and disinfect the protective light cone with a soft cloth wetted with a mild disinfectant solution, featuring a mild pH (pH 7) according to the manufacturer's specifications. **Allow the disinfectant solution to dry.**

8.3.1 PROTECTIVE LIGHT CONE – Inspection before the sterilisation

Before proceeding with the sterilisation process, carefully check the protective light cone for damaged surfaces, veins discolouratio and contamination.

WARNING

Do not *use a damaged protective light cone. If damage is apparent, replace the protective light cone with a new one.*

A damaged protective light cone cannot provide enough protection from the unit light.

If the protective light cone is still contaminated, repeat the cleaning and disinfection.

8.4 LIGHT GUIDE and PROTECTIVE LIGHT CONE – Packaging before the sterilisation

The light guide and the protective light cone can be sterilised by using a single-use medical steam sterilisation pouch of the appropriate size.

CAUTION

The light guide and the protective light cone must be packed individually in a single pouch.

When sterilising multiple instruments in one autoclave, ensure that the autoclave maximum load is not exceeded.

WARNING

Ensure that the inner pouch is large enough to contain the single instruments, without stressing the seals or tearing the packaging.

8.4.1 LIGHT GUIDE and PROTECTIVE LIGHT CONE – Sterilisation

8.4.1.1 Sterilisation method

- Carry out the sterilisation by means of a pre-vacuum steam autoclaving.

CAUTION

Never use *any other sterilisation method, because of potential incompatibility with the materials with which is made the lig guide.*

DO NOT USE the following sterilisation methods: *Ethylene oxide sterilisation, hot air sterilisation, flash autoclaving, STERRAD sterilisation, STERIS system or comparable sterilisation systems.*

DO NOT sterilise the light guide and the protective light cone by using: *Hydrogen peroxide, peracetic acid system, formaldehyde and glutaraldehyde sterilisation.*

8.4.1.2 Sterilisation parameters

- Minimum sterilisation parameters that provide a 10^{-6} sterility assurance level – (SAL).

Cycle Type	Minimum Temperature	Minimum Exposure Time (pouch)	Minimum Dry Time
Pre-vacuum	132°C + 3°C (270°F + 5°F)	4 minutes	20 minutes

CAUTION

Do not exceed 135°C (275°F).

8.5 HAND PIECE – Cleaning and disinfection

WARNING

The hand piece ***is not protected*** *against the penetration of liquids.*

Do not *spray liquids directly onto the surface and charging contacts of the hand piece.*

*Cleaning and disinfectant agents **must not** enter the hand piece!*

***NEVER** immerse the hand piece in liquids.*

***NEVER** clean the hand piece under running water.*

Do not** sterilise the hand piece. **Risk of serious damage, electrical shock and fire!

Clean and wipe the hand piece casing with a clean, soft lint free cloth dampened with a mild surface disinfection agent, featurin a neutral pH (pH7) according to the manufacturer's specifications.
Allow the disinfectant solution to dry or dry the residual disinfectant on the hand piece casing with a soft lint free cloth.

CAUTION

***Do not** use solvents such as acetone, isopropyl alcohol, and hydrogen peroxide, chloride, iodine, bromide, phenol or othe aggressive solutions to clean and disinfect the plastic surface of the hand piece. These substances may be harmful, caus discolouration and / or damage to the plastic materials of the hand piece.*

Do not use abrasive cleaners!

IMPORTANT: Cleaning of the charging contacts of the hand piece

After having carried out the cleaning / disinfection of the hand piece's plastic casing, always clean the charging contacts which are positioned in the bottom part of the hand piece. The charging contacts of the hand piece must always be free fr possible soil, composite and cleaning / disinfectant residues.

IMPORTANT

The hand piece charging contacts must be cleaned regularly (at least once a week) and always after having carried out th cleaning and disinfection of the hand piece plastic casing. Dirty charging contacts or contacts exposed to liquids, like cleaner or disinfectants, can negatively affect the charging process and prevent the battery of being charged.

Clean the charging contacts of the hand piece with an alcohol dampened soft lint free cloth or cotton swab.

CAUTION

***Do not** use sharp or pointed instruments to clean the hand piece contacts, since they could scratch and damage their surface and thus worsen the conductivity with the charging contacts.*

Before re-using the hand piece make sure that the hand piece's surface and the charging contacts are perfectly dried. If necessary, dry the contacts by blowing air onto them with compressed air.

8.6 CHARGING UNIT – Cleaning casing

DISCONNECT FROM MAINS

Disconnect the input power supply from the power outlet and charging unit prior to cleaning / disinfection.

WARNING

*The charging unit casing **is not protected** against the penetration of liquids.*

Do not *spray liquids directly onto the surface of the charging unit casing.*

CAUTION

DO NOT *sterilise the charging unit. It will no longer function and may cause a* ***risk of serious damage, electrical shock and fire!***

Do not *use solvents such as acetone, isopropyl alcohol, and hydrogen peroxide, chloride, iodine, bromide, phenol or other aggressive solutions to clean the plastic surface of the charging unit. These substances may be harmful, causing discolouration and / or damage to the plastic materials of the charging unit.*

Do not use abrasive cleaners!

Clean and wipe the charging unit casing with a clean, soft, lint free cloth dampened with a mild surface cleaning agent, featuring neutral pH (pH7) according to the manufacturer's specifications.

Dry the charging unit casing with a clean, non-abrasive cloth.

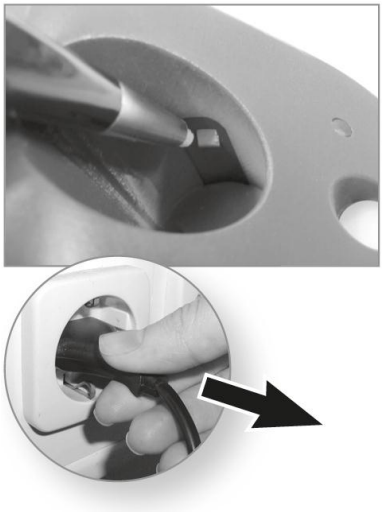
CAUTION

Be sure to dry the charging unit after cleaning. Moisture inside the unit could cause damage.

IMPORTANT

Upon completion of the cleaning procedure, make sure that the charging contacts inside the charging unit are perfectly dry. If necessary, dry the contacts by blowing air onto them with compressed air.

8.6.1 CHARGING UNIT – Cleaning charging contacts



IMPORTANT

After having carried out the cleaning of the charger's plastic casing, always clean the charging unit contacts. The charging contacts of the charging unit must always be free from possible soil, composite and cleaning residues.

The charging unit contacts must be cleaned regularly (at least once a week) and, in any case, always after having carried out the cleaning of the plastic casing. Dirty contacts or contacts exposed to liquids, like cleaner or disinfectants, can negatively affect the charging process and prevent the battery of being charged.

Clean the contacts of the charging unit with an alcohol dampened soft lint free cloth or cotton swab.

CAUTION

Do not *use pointed or sharp objects to clean the charging unit contacts!*

Do not *spray or flood the contacts with liquids!*

Do not *bend or modify the shape of the charging unit contacts during cleaning.*

Make sure that the charge contacts remain dry after cleaning and are not contacted by metallic and greasy parts. If necessary, dry the contacts by blowing air onto them with compressed air.

8.6.2 CHARGING UNIT – Replaceable charging contacts

Damaged or highly soiled charging unit contacts (that cannot be cleaned by following the procedures described in the above paragraph) can prevent the contacts' conductivity and consequently the battery charging.
In this case it is possible to replace the damaged charging unit contacts with new ones.
For additional information regarding replacement of charging unit contacts and spare part supply please contact your local Heraeus Kulzer subsidiary.

Working instructions:

Required tool: screwdriver for Phillips-Screws, mid-size.

1. Remove hand piece out of charger base.
2. Disconnect charger from mains.
3. Unplug connecting wire from charger.
4. Turn charger upside down.
5. Remove 2 screws from the charging contact bridge (see rear fold-out cover, **point 12**).
6. Pull out charging contact bridge.
7. Insert new contact bridge and fix / connect in reverse way.

CAUTION

Do not bend or contaminate the new contact bridge! Do care about perfect insert and fixation! Do not over tight the screws!

9 Shelf storage

Storage of the hand piece with battery during extended periods of non-use. Before or after a long inactivity period, fully charge the battery or store it in the operating charging unit. Although the built-in safety circuit of the battery prevents the full discharge, it is strongly recommended to fully charge the battery at least once every 5 months after inactivity.

10 Disposal

NOTE – IMPORTANT

The device must not be disposed off in normal domestic waste.

For the disposal of spare parts, or the unit, please contact the Heraeus Kulzer subsidiary directly in your country.

Dispose unserviceable batteries and light guides according to the corresponding legal requirements in your country.

WARNING – Damaged or exhausted battery disposal

Dispose a damaged or exhausted battery after taking the necessary steps to prevent external short circuit by the following method:

After having insulated the terminals of the battery with tape dispose off in accordance with your local council.

The conditions and precautionary measures for disposing of the device are subject to the valid legal provisions similar to any other electronic device which has become unusable (WEEE).

WEEE – Disposal of old equipment according to WEEE

Electrical and Electronic Equipment Act (ElektroG)

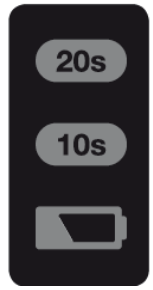
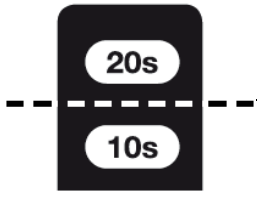
11 Troubleshooting

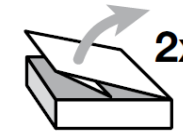
WARNING

If the below steps do not solve the problem, contact Heraeus Kulzer or a local authorised Customer Service agent: ***DO NOT USE*** *the Translux Wave and* ***DO NOT ATTEMPT*** *to service the unit as it may cause serious injury.*

If the device does not seem to be working properly, read this user manual again and then check the following table:

PROBLEM	POSSIBLE CAUSE	REMEDY
The charging unit does not power on. The GREEN LED ⊙ on the charging unit is switched off.	The input power supply is not connected to electrical supply outlet and / or to the charging unit power socket.	Make sure that the input power supply is securely connected to electrical supply outlet and to the charging unit power socket.
	Power outlet carries no voltage.	Use a different power outlet.
	The interchangeable adapter is not properly inserted into the input power supply casing.	Carefully read paragraph 5.2 of this user manual.
	The power cable of the input power supply is damaged.	Replace the input power supply with a new one. (The input power supply and its cord cannot be separated from each other.)
	The input power supply is defective.	Replace the input power supply with a new one.
	The charging unit is defective.	Contact Heraeus Kulzer or local authorised Customer Service agent.
	The charging unit contacts are short-circuited.	Eliminate the cause of short circuit. If the short circuit condition persists, replace the charging unit contacts with new ones. Make reference to paragraph 8.6.2.
Hand piece NOT inserted into the charging unit. The light emission does not start when the "**Start / Stop**" button ⏻ is pressed and no information appears on the hand piece's display.	**Hand piece without battery.**	Insert the battery into the hand piece (see paragraph 5.3).
	Hand piece in "**Sleep Mode**".	Press the "**Start / Stop**" button to bring the hand piece out of the "**Sleep Mode**". Make reference to paragraph 6.3.
	Empty battery. There is not enough charge in the	Place the hand piece in the charging unit and re-charge the battery (see paragraph

	battery to turn on the hand piece.	5.5).
	Electronics malfunction.	Contact Heraeus Kulzer or local authorised Customer Service agent.
	Defective battery.	To verify if the battery is defective, place the hand piece in the charging unit. A "**prequalification sequence**" starts in which Translux Wave micro-processor checks the battery status. This prequalification sequence can last up to max. 30 minutes. If, during this check sequence, a "**beep**" signal is emitted every second for a period of 30 seconds and the battery icon on the hand piece is blinking YELLOW, the battery is detected to be defective. **Replace the battery with a new one** (see paragraph 5.3).
"**2 beeps**" are emitted at the end of the exposure cycle.	**Low battery charge.**	The "**2 beeps**" signal that the residual charge level of the battery is adequate only for a few subsequent exposure cycles. Place the hand piece in the charging unit and re-charge the battery (see paragraph 5.5).
The light emission does not start when the "**Start / Stop**" button is pressed. The curing LED on the hand piece in use starts blinking GREEN.  **blinking**	**The LED pack is defective.**	Contact Heraeus Kulzer or local authorised Customer Service agent.
After several consecutive exposure cycles, the light emission does not turn on, when the "**Start / Stop**" button is pressed, and "**3 beep**" signals are emitted.	**Overheating protection.** The hand piece has become overheated in the course of use and the temperature overload sensor has activated. The activation of the overheat	Allow the hand piece to cool down for at least 4 – 5 minutes, then start the next exposure by pressing the "**Start / Stop**" button. **Note:** The hand piece upon reaching

	protection temporarily prevents (for a few minutes) the use of the unit.	operational temperature. **No "manual reset"** required.
During an exposure cycle "**3 beeps**" are emitted.	**Overheating protection.** The hand piece has become overheated in the course of use and the temperature overload sensor has activated. The activation of the overheat protection temporarily prevents (for a few minutes) the use of the unit.	Allow the hand piece to cool down for at least 4 – 5 minutes, then start the next exposure by pressing the "**Start / Stop**" button.
Malfunctions during charging phase. A "**beep**" signal is emitted every second for a period of 30 seconds and the battery status LED on the hand piece blinks YELLOW. **blinking**	During the battery pre-qualification phase (battery condition: completely empty ref. paragraph 4.2.4 and 5.5). The electronics detects a defective or malfunction status of the battery and interrupts the charging process.	Replace the battery with a new one (see paragraph 5.3). 
Hand piece placed in the charging unit but the charging phase does not start. The green battery status LED on the hand piece is off.	**Defect:** interrupt of charging contacts.	See paragraph 8.5 and 8.6.2.
	Improper contact between the charging base and the hand piece.	Check if the hand piece has been inserted in the correct orientation into the charging unit. **Alignment key.** Make reference to the paragraph 4.2.1, points 4 and 5.
	Charging and / or hand piece contacts are soiled.	Clean the hand piece and the charging unit contacts. Make reference to the paragraphs 8.5 and 8.6.1.
The light intensity measured with the meter integrated in the charging unit is insufficient. The LED ☀ on the charging unit lights YELLOW.	Light guide not properly inserted into the hand piece.	Check light guide for complete insertion in metal cone of the hand piece.
	Light guide output contaminated by foreign material or composite residues that can interfere with light output.	Clean the light guide output. Make reference to paragraph 8.2.
	Light guide damaged or aged.	Replace the light guide with a new one.

12 Technical specifications

Classification according to Directive 93/42/EEC: Class I (one)

Safety Standards: The product has been tested and found to comply to IEC 60601-1 (second edition) and to IEC 60601-1-1.
The product has been tested and found to comply to IEC 60601-1 (third edition) and to IEC 60601-1-2 (third edition – for electromagnetic compatibility – EMC).
The hand piece is intended for use within the patient environment whereas th charger unit and the power supply adapter are not intended for use within the patient environment.
Note: The patient environment is defined as an area 1.5 m from the patient (as per IEC 60601-1, third edition and IEC 60601-1-1).

Classification according to IEC 60601-1: Class II, Type B, **Applied Part**: Light guide with protective cone.
IP 20 (Charging unit).
IP 20 (Translux Wave)

Charging unit: Translux Wave Charging unit

Power supply for the charging unit: Switching Power Supply (Direct Plug-In) manufactured by:
Phihong Technology CO LTD – **Model**: PSACO5R-050.
Input: 100 – 240 V ~ – 300 mA – 50 / 60 Hz –.
Output: 5 V ⎓ – 1 A Max – ⊖—●—⊕ .
Class II equipment

Power supply for the hand piece: Rechargeable Lithium-ion battery.
Manufacturer: Panasonic.
Model: NCR-18500.
Nominal Voltage: 3.6 V.
Nominal capacity (Typical): 2000 mAh

Hand piece: **Model**: Translux Wave.
Operation: Intermittent service: 120" ON – 40“ OFF – max 2 times running

Light source: High-luminosity LED.
Class 2M LED Product (IEC 60825-1).
Wavelength range: 440 – 480 nm

Light guide: Lead-free multi core rod, 8 mm diameter.
Sterilisable in pre-vacuum steam autoclave:
4 minutes (minimum) at minimum temperature of 132°C + 3°C (270°F + 5°F)
Max. 500 cycles

Settable exposure cycles:

– **Normal exposure** 10 seconds of exposure time.

Acoustical signals:

1 beep at the start of exposure.

1 beep at the end of exposure

– **"Soft-Start" exposure**

20 seconds of exposure time. (The "**Soft-Start"** means increase of light intens from 50% up to 100% within 2 seconds.)

Acoustical signals:

1 beep at the start of exposure.

1 beep after 1 second for indication of "**Soft-Start"-**mode activation.

1 beep after 10 seconds of exposure.

1 beep at the end of exposure

Charging time of empty battery:

Approx. 3 hours

Environmental conditions of unit:

	Operation	**Transportation and storage**
Temperature	10°C – 35°C (50°F – 95°F)	–20°C – 40°C (–4°F – 104°F)
Relative humidity	45% – 85%	45% – 85%
Atmospheric pressure	800 – 1060 hPa	500 – 1060 hPa

Weight and dimensions:

Charging unit: weight 450 g.

Dimensions: L 140 x W 58 x H 62 mm

Hand piece: weight 150 g (incl. light guide).

Dimensions: L 275 mm, max. Ø 24 mm

12.1 Electromagnetic compatibility EN 60601-1-2

WARNING

The device requires specific EMC precautions and must be installed and started up in accordance with the EMC information given in this paragraph.

Portable and mobile radio communication appliances may affect the correct function of the device.

Guidance and manufacturer's declaration – Electromagnetic emissions		
The Translux Wave is intended for use in the electromagnetic environment specified below. The customer or the user of the Translux Wave should ensure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment – Guidance**
RF emissions CISPR 11	Group 1	The Translux Wave uses RF energy only for its internal function. Therefore it's RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The Translux Wave is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Complies	

Guidance and manufacturer's declaration – Electromagnetic immunity			
The Translux Wave is intended for use in the electromagnetic environment specified below. The customer or the user of the Translux Wave should ensure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – Guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	The device continues to work regularly and in safety.	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient / burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input / output lines	The device continues to work regularly and in safety.	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	The device continues to work regularly and in	Mains power quality should be that of a typical commercial or hospital

		safety.	environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	< 5% U_T (> 95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycle 70% U_T (30% dip in U_T) for 25 cycle < 5% U_T (> 95% dip in U_T) for 5 sec	The device can vary from the required levels of immunity with a duration for as long as the device remains in safety; no malfunctions have been detected and can be restored to pre-test status with the intervention of the operator.	Mains power quality should be that of a typical commercial or hospital environment.
Power frequency (50 / 60 Hz) magnetic field IEC 61000-4-8	3 A / m	The device continues to work regularly and in safety.	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE: U_T is the a.c. mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration – Electromagnetic immunity			
The Translux Wave is intended for use in the electromagnetic environment specified below. The customer or the user of the Translux Wave should ensure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – Guidance**
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 V_{eff} 150 kHz to 80 MHz 3 V / m 80 MHz to 2.5 GHz	The device continues to work regularly and in safety.	Portable and mobile RF communications equipment should be used no closer to any part of the disposal including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** d = 1.2 √P d = 1.2 √P 80 MHz to 800 MHz d = 2.3 √P 800 MHz to 2.5 GHz where (**P**) is the maximum output power rating of the transmitter in watts (**W**) according to the transmitter manufacturer and (**d**) is the recommended separation distance in metres (**m**). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range (**b**). Interference may occur in the vicinity of equipment marked with the following symbol:

Notes:

(1) At 80 MHz and 800 MHz, the higher frequency range applies.

(2) These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

a) Field strengths from fixed transmitters, such as base stations for radio (cellular / cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Translux Wave is used exceeds the applicable RF compliance level above, the Translux Wave should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Translux Wave.

b) Over the frequency range 150 kHz to 80 MHz field strengths should be less than 3 V / m.

Recommended separation distances between portable and mobile RF communications equipment and the Translux Wave

The Translux Wave is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Translux Wave can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Translux Wave as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter **(W)**	Separation distance according to frequency of transmitter (**m**)		
	150 kHz to 80 MHz $d = 1.2 \sqrt{P}$	80 MHz to 800 MHz $d = 1.2 \sqrt{P}$	800 MHz to 2.5 GHz $d = 2.3 \sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

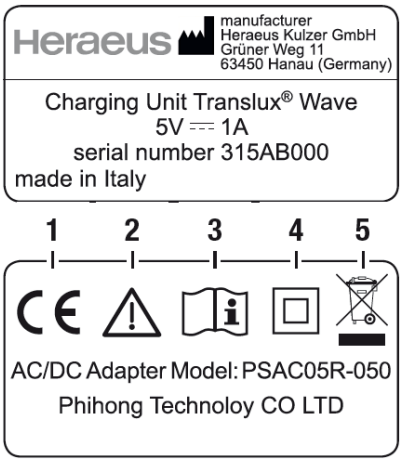
For transmitters rated at a maximum output power not listed above, the recommended separation distance (**d**) in metres (**m**) can be estimated using the equation applicable to the frequency of the transmitter, where (**P**) is the maximum output power rating of the transmitter in watts (**W**) according to the transmitter manufacturer.

Notes:

(1) At 80 MHz and 800 MHz the separation distance for the higher frequency range applies.

(2) These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

12.2 Charging unit identification plate



Description of the symbols on the identification plate

1 CE mark.

2 Caution, consult accompanying documents.

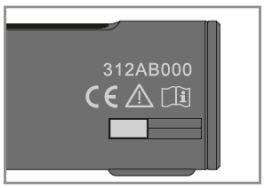
3 Consult instructions for use.

4 Double insulation (device complies with safety class II).

5 Disposal of old electrical and electronic equipment.
(Applicable in the European Community and other European countries with separate collection systems.)

12.3 Hand piece serial number

The hand piece serial number is engraved on the bottom part of its casing.



Engraved serial number.

13 Warranty

Each Heraeus Kulzer unit is subject to a stringent check and final inspection prior to delivery to guarantee perfect operation of the equipment. For all new Heraeus Kulzer products purchased from a Heraeus Kulzer retailer or importer, Heraeus Kulzer offers a warranty of 2 (two) years from the day of purchase for material and production faults. During the warranty period, Heraeus Kulzer undertakes to repair (or replace, if it chooses) parts of the products deemed by Heraeus Kulzer to be faulty, free of charge.
No provision has been made for complete replacement of the Heraeus Kulzer products.

Under no circumstances shall Heraeus Kulzer be liable for any direct or indirect personal injury or damage in the following cases:

- The unit was not used for its intended purpose.
- The unit was not used according to the instructions and specifications described in this manual.
- The electrical installation in the rooms in which the unit is used does not comply with existing legislation and relevant specifications.
- The assembly, additions, setting, alteration and repair was not performed by Heraeus Kulzer specialist personnel.
- The conditions for storing the unit do not comply with the specifications listed in paragraph 12 (Technical specifications).

Excluded from the warranty are transportation damage, damage caused by improper use or negligence, damage caused by connection to a power supply other than that specified for the equipment and damage to the control lamps, buttons and all accessories. The warranty shall become invalid if the unit is altered or repaired by personnel not belonging to Customer Service. When making a warranty claim, the customer forwards the damaged unit, at his own cost, to the retailer or Heraeus Kulzer importe where he bought the unit. The unit, including the accessories, must be well packed before shipping (if possible, in the original packaging).

A card containing the following information must be enclosed with the unit if returning the unit:

a) Name, address and telephone number of owner.

b) Name and address of retailer / importer.

c) Photocopy of the delivery note / purchase receipt for the unit by the owner which shows the date, designation and serial numbe the unit.

d) Description of malfunction.

The warranty does not cover transportation or any transportation damage.

In the event of damage caused by an accident or improper use, or which occurs after expiration of the warranty period, repairs will invoiced according to effective material and labour costs.

14 Service

14.1 Service agents / Contact in the countries

15 Document history

2012-08 Draft version for Prototypes.

2013-08 First edition.

Subject to modifications. Dated: 2013-08